

REMARKS

Claims 1-18, 23-27, 33, 34, 39, 40, 42, 44 and 47 are currently amended. Claim 46 is canceled. Claims 64-66 are new. Reconsideration of the pending claims is requested in light of the amendments above and remarks below.

I: The Objection to Claim 42

Claim 42 is currently amended. Reconsideration is urged.

II: The Rejection of Claims 1, 2, 4, 8-10 and 17-47 under 35 U.S.C. 112 (written description)

Claims 1, 2, 4, 8-10 and 17-47 stand rejected under 35 U.S.C. 112 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office alleges, without any scientific evidence or reasoning, "2μm-family plasmid" representing a genus of plasmids was not in possession of the Applicant at the time of filing. Applicants traverse this rejection.

Section 112, first paragraph provides that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same....

The written description requirement of 35 U.S.C. § 112, first paragraph, is fulfilled when the patent specification describes the claimed invention in sufficient detail such that the claim limitations are described so that one of skill in the art would recognize that the applicants had invented the subject matter. See *Vas-Cath, Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); *In re Herschler*, 591 F.2d 693, 700 (C.C.P.A. 1979). The written description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See *In re Marzocchi*, 169 U.S.P.Q. 367 (CCPA 1971).

The written description requirement can be met by showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with known or disclosed correlation between function and structure, or some combination of

such characteristics. See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002). A description of a claimed genus may be achieved by recitation of a representative number of species falling within the scope of the genus or by a recitation of structural features common to the members of the genus which constitute a substantial portion of the genus. See *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d at 1569.

The Patent Office's *Written Description Training Materials*, Revision 1, (March 25, 2008), also provides guidance as to how to determine if there is sufficient written description to inform the artisan that the applicant was in possession of the claimed genus at the time the application was filed. These guidelines instruct that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. For example, the Written Description Guidelines expressly state "The number of species required to represent a genus will vary, depending on the level of skill and knowledge in the art and the variability among the claimed genus. For instance, fewer species will be required where the skill and knowledge in the art is high, and more species will be required where the claimed genus is highly variable." See pages 1-2.

The Examiner is incorrect that the use of the term "2μm-family plasmid" does not serve to describe the claimed genus in a manner which allows the species to be distinguished from other plasmids. Initially, Applicants note that he specification describes known 2μm-family plasmid species, including pSR1, pSB3 or pSB4 from the yeast cell *Zygosaccharomyces rouxii*, pSB1 or pSB2 from the yeast cell *Zygosaccharomyces bailli*, pSM1 from yeast cell *Zygosaccharomyces fermentati*, pKD1 from the yeast cell *Kluyveromyces drosophilarum*, pPM1 from the yeast cell *Pichia membranaefaciens*, and the 2μ plasmids from the yeast cell *Saccharomyces cerevisiae* or *Saccharomyces carlsbergensis*. Further, Figure 1 shows a diagram of a 2μm-family plasmid. Any assertion by the USPTO that additional plasmids must be taught or described in the specification is clearly inaccurate. In fact, all 2μm-family plasmids were envisioned by the Applicants in filing the patent application and clearly in the possession of the Applicants. Importantly, the detailed description describes 2μm-family plasmid(s) of the present disclosure beginning on page 7, ln. 1 through page 8, ln. 4. Further, page 6 describes examples of suitable 2μm-family plasmid to be those as described in Volkert *et al*, *Deoxyribonucleic Acid Plasmids in Yeast*, *Microbiological Reviews*, 53(3), 299-317 (1989). Volkert confirms that since the 1980s, a term such as 2μm-family plasmid has been recognized. For example Volkert uses the term 2μm circle like plasmids of Yeast. Utata (1987) futher uses the term "Yeast plasmids resembling 2 μm DNA". Accordingly, the references support the

present disclosure that a circular plasmid from yeast is a 2 μ m-family plasmid. One of ordinary skill in the art would recognize the term 2 μ m-family plasmid relates to circular yeast plasmids. Volkert even explains that few plasmids (linear or circular) have been identified in yeasts (Volkert, p305, column 2, last paragraph to p. 306, column 1, first full paragraph). All of the identified circular plasmids have been classified as 2 μ m family plasmids (See Volkert, p306, column 1, first full paragraph and p312, column 2, first paragraph).

Once apprised of the present disclosure it would be routine for one of ordinary skill in the art to obtain circular plasmids from yeast and produce plasmids of the present disclosure. The knowledge in the art is high, in a field where the level of skill in the art is high. Thus, the species mentioned are a representative number of species within the scope of the genus and therefore Applicants' disclosure evidences that Applicants were in possession of the claimed genus of plasmids at the time the application was filed.

Moreover, an artisan would reasonably conclude that Applicants were not only in possession of the identified species of 2 μ m-family plasmid, but also that Applicants had possession of highly related 2 μ m-family plasmid(s), as specified by the claims. Indeed, based on the high level of skill in the art, the phrase "2 μ m-family plasmid" itself conveys to the artisan that Applicants were in possession of the claimed invention.

The Examiner has not provided any evidence that one skilled in the art would not be able to identify the claimed plasmids. Indeed, one of ordinary skill in the art would easily be able to identify a plasmid as a 2 μ m-family plasmid. Accordingly, Applicants have provided a precise definition of the genus of plasmids sufficient to distinguish it from other plasmids.

In sum, Applicants' specification provides (1) a precise definition by structure of the genus of plasmids sufficient to distinguish it from other plasmids and (2) a description of numerous representative members of the genus, in sufficient detail so that one of skill in the art would recognize that Applicants had invented the claimed subject matter. Further, identifying a species as a 2 μ m-family plasmid is routine to one of skill in the art, and clearly in Applicants' possession at the time of filing. Accordingly, Applicants respectfully submit that the rejection of claims 1, 2, 4, 8-10 and 17-47 as failing to comply with the written description requirement is in error.

Notwithstanding the above, the Examiner has not provided sufficient evidence or reasoning to rebut that the specification provides an adequate written description for highly related 2 μ m-family plasmid(s) as claimed. In this regard, additional representative species are not required to be disclosed. Given the high degree of relatedness recited in the claims, an extremely high degree of predictability exists as to the structure and function of the 2 μ m-family plasmids falling within the claims.

Therefore, Applicants respectfully submit that the specification contains a sufficient description of the structural and functional characteristics of the claimed 2 μ m-family plasmid(s) to fulfill the requirements of 35 U.S.C. 112. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

III. The Rejection of Claims 7, 12 and 23-27 under 35 U.S.C. 112 (written description)

Claim 7 is currently amended. Reconsideration is urged.

Claim 12 is currently amended. Reconsideration is urged.

Claims 23-27 are currently amended. Reconsideration is urged.

As Claims 7, 12 and 23-27 are each currently amended; Applicants submit they have been fully responsive to the Examiner's rejections.

IV. The Rejection of Claims 1-47 under 35 U.S.C. 112, second paragraph (indefinite)

Initially, Applicants note that the term "2 μ m-family plasmid" is clear. One of ordinary skill in the art understands that a 2 μ m-family plasmid is any circular plasmid obtained from yeast. All of the identified circular plasmids have been classified as 2 μ m-family plasmids. See for example the detailed description describing 2 μ m-family plasmid(s) of the present disclosure beginning on page 7, ln. 1 through page 8, ln. 4. See also Volkert *et al*, Deoxyribonucleic Acid Plasmids in Yeast, *Microbiological Reviews*, 53(3), 299-317 (1989) at p306, col. 1, first full paragraph and p312, col. 2, first paragraph. Applicants submit the terminology is clear. Reconsideration is urged.

Claims 2, 4, 10 and 16 are currently amended. Reconsideration is urged.

Claim 3 is currently amended. Reconsideration is urged.

Claims 7, 12 and 23-27 are currently amended. Reconsideration is urged.

Claims 9 and 23 are currently amended. Reconsideration is urged.

Claims 10, 16 and 33 are currently amended. Reconsideration is urged.

Claims 18, 33 and 34 are currently amended. Reconsideration is urged.

Claim 39 is currently amended. Reconsideration is urged.

Claim 40 is currently amended. Reconsideration is urged.

Claim 44 is currently amended. Reconsideration is urged.

V. New Claims 64-66

New Claims 64-66 is added. No new matter is added. Should any additional fees be due the USPTO is authorized to charge the deposit account of Novozymes North America, Inc. *i.e.*, Deposit Account No. 50-1701.

VI. Conclusion

The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application. Should any additional fees be due the USPTO is authorized to charge the deposit account of Novozymes North America, Inc. *i.e.*, Deposit Account No. 50-1701.

Respectfully submitted,

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